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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,224	06/05/2006	Frode Brakstad	VITL0101PUSA	3744
22045	7590	12/12/2007		
BROOKS KUSHMAN P.C. 1000 TOWN CENTER TWENTY-SECOND FLOOR SOUTHFIELD, MI 48075			EXAMINER HUANG, GIGI GEORGIANA	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 12/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/596,224	Applicant(s) BRAKSTAD ET AL.	
	Examiner GiGi Huang	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/7/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. Claims 1-8 are present for examination at this time.

Information Disclosure Statement

2. The information disclosure statement filed August 7, 2007 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because there is no translation of certain documents indicated on the IDS. It is noted that some of the documents are present on the International search report but cannot be considered without an available translation present. It is requested that if consideration is desired, that a translation of the documents be submitted. The indicated documents have been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Objections

3. Claims 1-5 are objected to because of the following informalities: the word "lest" is misspelled and presumed to be "least". Appropriate correction is required.

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4. Claim 2 is objected to because of the following informalities: the range "0,5-30mg, 0,1-10mg" utilize commas and presumed to be periods. Appropriate correction is required.

5. Claim 4 are objected to because of the following informalities: the phrase "vitamin E as antioxidant" is missing "an" or "the" before "antioxidant". Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The term "C₁₋₈ carboxylic acid" is not adequately described to convey what comprises the term "C₁₋₈ carboxylic acid", if the structure is straight, if it is branched, if it is a single ring, if this more than one ring, if there are substitutions, if there are heterocycles, if it is alkyl, if it is aryl, if there are combinations of rings and branches, it does not begin to adequately describe the term for one skilled in the art to envision. It is unclear what would be encompassed by the terms as addressed in the 112, 2nd paragraph rejection below.

Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description for benzoic acid and to a degree formic-, citric-, lactic-, propionic-, ascorbic-, and fumaric- acid. The formic-, citric-, lactic-, propionic-, ascorbic-, and fumaric- acids are themselves unclear as to what the hyphen is indicating. It is unclear if the hyphens is an indicator for the word "acid" or if it is open to additional substitutions which would not be sufficient written description themselves as species. Based on the compounds identified in the specification, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "C₁₋₈ carboxylic acid" is not defined by the claims, the specification does not allow one of ordinary skill in the art to be reasonably apprised of the scope of the invention. It is unclear what is the "C₁₋₈ carboxylic acid"

and does not allow one of skill in the art to ascertain the metes and bounds of the invention. For purposes of prosecution, any compound that has eight carbons or less with a carboxylic group will fulfill the claims.

10. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "dry" in claims 1-5 is a relative term which renders the claim indefinite. The term "dry" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Most compositions have some degree of moisture unless freeze-dried for instance, which will vary widely, depending on the working, storage, and processing conditions. It is unclear what the circumstances are, the requisite degree, and does not allow one of skill in the art to ascertain the metes and bounds of the invention.

Additionally, the term "dry weight of the supplement" is not defined by the claims, the specification does not allow one of ordinary skill in the art to be reasonably apprised of the scope of the invention. It is unclear what is the "dry weight of the supplement" and if the amounts addressed, include or exclude the vitamins as part of the supplement weight stipulated in the claims. It is also unclear what the "dry weight" would be as most compositions have varying degrees of moisture depending on the working, storage, and processing conditions. It is unclear what the circumstances are and does not allow one of skill in the art to ascertain the metes and bounds of the invention.

For purposes of prosecution, any amount of vitamins B6, B9, and B12 will apply to the claims.

11. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "weight%" is unclear what the basis of the weight percentage is. It could be the entire the composition, the supplement without the vitamins, or of the iron as a starting point. It does not allow one of skill in the art to ascertain the metes and bounds of the invention.

For purposes of prosecution, if the component is present in the composition, it meets the claims.

12. Claims 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6-8 provides for the use of a supplement, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 6-8 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under

35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Based the rejections addressed above, claims 6-8 are not further treated on the merits.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Bailey et al. (U.S.Pat Pub. No. 2002/0150653).

Bailey et al. teaches the concept of a food, feed, and vitamin preparations comprising folates and multivitamins. The compositions were preferably stored with antioxidants and reducing agents to extend shelf life. The pH of the final composition can be optimized based on the desired stability properties, preferably with an acidity less than about pH 4. The compositions exemplified comprised citric acid, ascorbic acid, vitamin E, pyridoxine (vitamin B6), folic acid (vitamin B9), vitamin B12 (cyanocobalamin), ferrous fumarate, and silica (desiccant).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Conclusion

15. Claims 1-8 are rejected.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GiGi Huang whose telephone number is (571) 272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH

Zohreh Fay (Primary Examiner)

A handwritten signature in black ink, appearing to read "Zohreh Fay", is written below the printed name.